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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ROCHE DIAGNOSTICS OPERATIONS INC. 9115 Hague Road Indianapolis, IN 46250-0457				
EXAMINER				
ALEXANDER, LYLE				
ART UNIT		PAPER NUMBER		
1797				
NOTIFICATION DATE		DELIVERY MODE		
06/30/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

marsha.breen@roche.com

karla.dirks@roche.com

jackie.pike@roche.com

### Office Action Summary

**Application No.**

10/581,409

**Applicant(s)**

PACHL ET AL.

**Examiner**

LYLE A. ALEXANDER

**Art Unit**

1797

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) 37-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-36 and 40-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 22-36 and 40-42, drawn to an analytical test device and method of use.

Group II, claim(s) 37-39, drawn to a method of forming a test strip using nanoparticles.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:  
The analytical device of group I does not require "nanoparticles" to make the surface hydrophobic.

3. Newly submitted claims 37-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: See the above restriction requirement

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Applicant is advised that should claim 40 be found allowable, claim 42 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 26 is not clear what is intended by "average distance between elevations". Is this a surface roughness type of characteristic?

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 22-25, 29-36 and 40-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Markart (USP 6,441,898).

Markart teaches an analytical test element(18) for the measurement of blood glucose. Column 5 lines 3+ describe the construction of the test strip in figures 2-4. The strip(18) comprises carrier web(26) that is covered with reagent/paint layer(34) and diaphragm strips(30) on both ends. The left end of the strip is a

surface(32) that is used for standardization. The area between the two diaphragm strips are the reaction field. There is an aperture(40) in the hydrophobic outer surface(38) where the blood sample is applied. Over the reaction field and below the aperture is the hydrophilic inner layer(36) that spreads the sample over layer(36). Figure 4 shows there is a gap between the inner layer(36) and the reaction field(34).

The Office has read the claimed "*inert carrier*" on the taught **web(26)**, the claimed "*application zone*" on the taught **opening(40)**, the claimed "*channel gap*" on the taught **gap between layer(36) and the reaction field** and the "*hydrophobic structure*" on the taught **outer surface(38)**.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markart et al.

See Markart et al. supra.

Markart et al. are silent to the claimed "distance between elevation ... 50nm-200 microns ... average height ... 50nm-100 microns ...", the hydrophobic surface energy less than or equal to 10nM/m and the hydrophobic contact angle greater than 120°.

MPEP 2144.05(II)(B) states that optimization of a result effective variable is ordinarily within the skill of the art. A result-effective variable is a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. See *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) and also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The selection of the surface roughness, is a result effective variable with the well known and expected results relating to the speed and turbulence of a fluid flow. The more rough the surface, the slower and more turbulent will be the fluid flow. It would have been within the skill of the art to modify Markart and make the surface have a roughness with a "distance between elevation ... 50nm-200 microns ... average height ... 50nm-100 microns ..." as optimization of a result effective variable to achieve the desired fluid flow speed and turbulence.

The selection of the surface energy and contact angle relate to the extent of hydrophobicity. Depending on the characteristics of the test fluid, such as viscosity, the hydrophobic characteristics of the surface will need to be optimized. It would have been within the skill of the art to further modify Markart to have a surface energy less than or equal to 10nM/m and the hydrophobic contact angle greater than 120° as optimization of a result effective variable to achieve the well known and expected results of the desired hydrophobicity for the specific type of sample

### ***Response to Arguments***

7. Applicant's arguments filed 5/4/10 have been fully considered but they are not persuasive.
8. Applicant states Markart teaches the outer surface(38) maybe hydrophobic, but fails to teach the claimed hydrophobic surface around the application zone. Markart teach in column 5 lines 37-40 the test strip is covered by a hydrophobic layer(38) and

has an opening(40) to receive the sample. The Office has equated the taught surface(38) to the claimed hydrophobic surface and the taught opening(40) to the claimed application zone. The Office maintains Markart clearly meets the claimed hydrophobic surface surrounding the sample application zone.

9. Applicant's remarks were convincing with respect to the 35 USC 102(b) rejections over CA 2095982 and these rejections have been vacated.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A. ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/  
Primary Examiner, Art Unit 1797